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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,580	01/18/2001	John C. Smith	P 0276522 PHM.70640/US	4676

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EXAMINER	
EINSMANN, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	7

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/761,580	SMITH ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to methods for the diagnosis of a polymorphism in PDH E2 in a human, classified in class 435, subclass 6.

II. Claims 3-6, drawn to isolated nucleic acids, classified in class 536, subclass 23.1.

III. Claim 7, drawn to the use of a polymorphism in a linkage study, classified in class 435, subclass 6.

IV. Claim 8, drawn to methods of treating a human in need of treatment, classified in class 424, subclass 94.1.

V. Claim 9, drawn to an allelic varient of the human PDH E2 polypeptide, classified in class 435, subclass 189.

VI. Claim 10, drawn to an antibody specific for an allelic variant of human PDH E2, classified in class 530, subclass 387.1.

VII. Claim 11-12, drawn to use of polymorphism in bioinformatic analysis, classified in class 702, subclass 19.

Further Restriction Requirement Applicable to All Groups

Each group detailed above reads on more than one patentably distinct group, wherein each of the distinct group is drawn to methods for the detection of separate polymorphisms, nucleic acids comprising different polymorphic variants, linkage studies of the different polymorphisms, treatment of a patient after diagnosis using more than one

polymorphism, polypeptides with distinct allelic sequences, antibodies to those polypeptides, and the use of distinct polymorphisms in bioinformatics. For example, group I above encompasses four different inventions, that is, methods for detecting each of the four different polymorphisms recited. For the elected group (of groups I-VII), applicants must further elect single polymorphism for examination in the appropriate product or method claim. For example, if applicant elects group I, applicant should further elect one of the polymorphisms for examination.

Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims.

The inventions are distinct, each from the other because of the following reasons:

2. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications.

3. Inventions I and II, inventions II and III, inventions II and IV, and inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of invention II can be used in other methods, such as to express the encoded

polypeptide, for nucleic acid purification assays and for aptamer assays. The claim set demonstrates that the nucleic acids can be used in a number of different methods such as in the diagnostics of group I, the linkage analysis of group III, the treatment methods of group IV, and the bioinformatic methods of group VII.

4. Inventions I, III, IV, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods with different goals, distinct method steps and requiring different reagents.

5. Inventions I and V, inventions I and VI, inventions III and V, inventions III and VI, inventions IV and V, inventions IV and VI, inventions VII and V, and inventions VII and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the products of inventions V and VI are not disclosed as being used in the methods of groups I, III, IV, or VII.

6. The inventions of Groups II, V and VI are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group II is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group V is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group VI is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure

that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups II, V and VI can be used in materially different processes, for example, the DNA of Group II can be used in hybridization assays, the antibody of Group VI can be used in immunoassay, the polypeptide of Group V can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups II, V, and VI are patentably distinct from each other.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VII require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

8. A telephone call was made to Glen Perry on 1/24/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1655

February 8, 2002

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP ~~1800~~ 1600